


CelgeneRiskManagement.com

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Welcome to the Celgene REMS Program

To avoid embryo-fetal exposure, Risk Evaluation and Mitigation Strategy (REMS) programs are mandatory for the Celgene products THALOMID® (thalidomide), REVLIMID® (lenalidomide) and POMALYST® (pomalidomide). The THALOMID REMS™ program (formerly known as the S.T.E.P.S.® program), REVLIMID REMS™ program (formerly known as the RevAssist® program), and POMALYST REMS™ program require prescribers and pharmacists to be certified and patients to enroll and comply with all of the requirements for each program.

If you would like to obtain more information about any of the Celgene REMS programs, please click on the program name below:

RevlimidREMS™
Visit www.REVLIMIDREMS.com,
to learn more about the
REVLIMID REMS™ program.

PomalystREMS™
Visit www.POMALYSTREMS.com,
to learn more about the
POMALYST REMS™ program.

THALOMIDREMS™
Visit www.THALOMIDREMS.com,
to learn more about the
THALOMID REMS™ program.

For prescribers, please enter your User Name and Password to manage your patients through a Celgene REMS program. If you do not have an online account, select Create User Account to establish an account. Patients currently enrolled in a Celgene REMS program are not required to create an online account to complete a survey. Please select Patient Surveys and enter the information requested to begin a survey.

To login to your account:

User Name

Password


[Forgot Password? >](#)

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Click on a button below to access the corresponding REMS menu of operations for that product: enroll a patient, access an existing or save a new Patient-Physician Agreement Form, complete a prescriber survey or write a prescription.

For **REVLIMID REMS™**
(formerly known as the RevAssist® program)




Please see full [Prescribing Information](#), including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.

For **POMALYST REMS™**



Please see full [Prescribing Information](#), including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.

For **THALOMID REMS™**
(formerly known as the S.T.E.P.S.® program)



Please see full [Prescribing Information](#), including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.

The Prescriber Dashboard is an optional resource that displays the status of patients under your care for a specific Celgene REMS program. A patient search function is also included to access detailed patient history information.

Select the "Manage My Account" button to view your Celgene REMS online account information.

[Prescriber Dashboard](#) [Manage My Account](#)

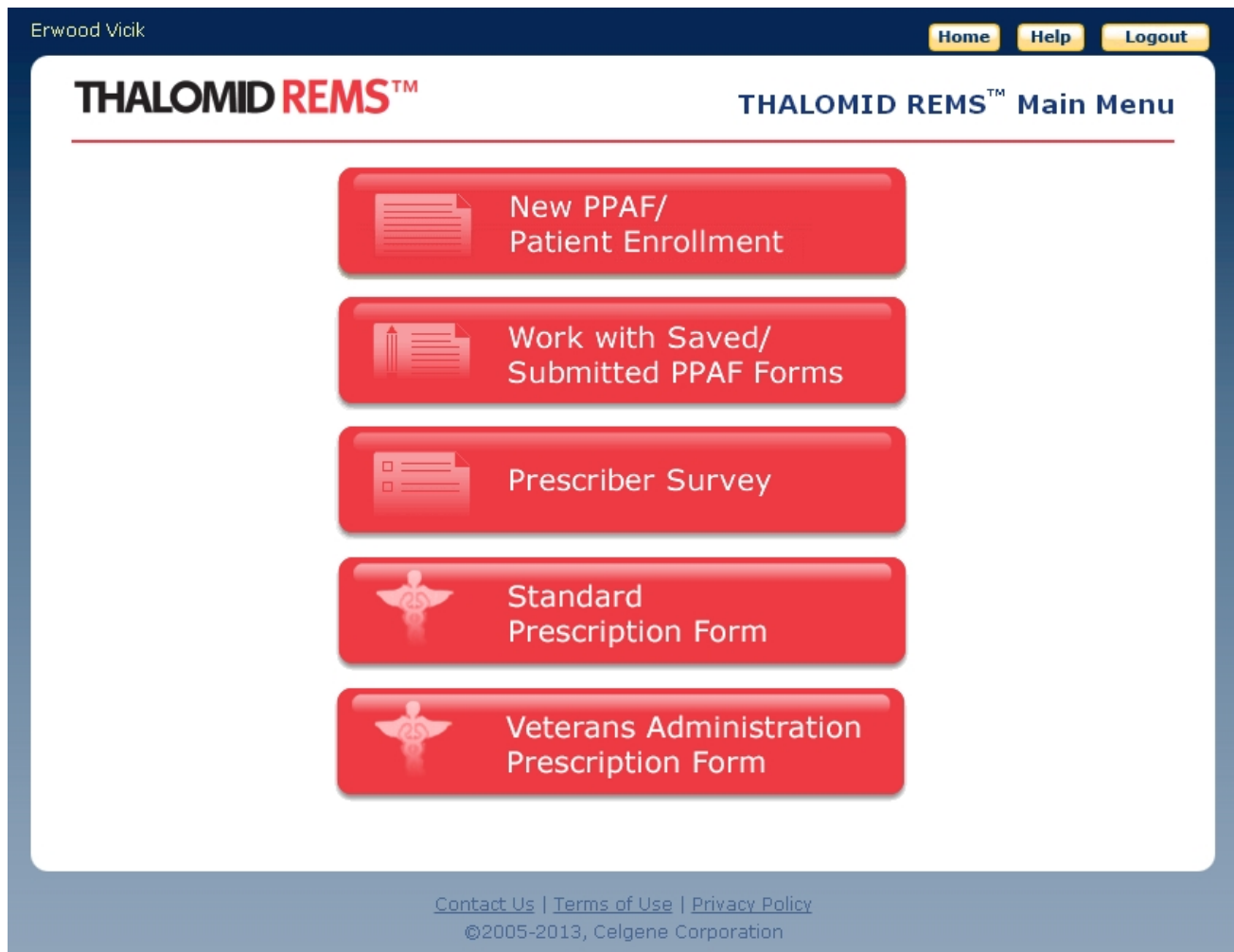
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Reference ID: 3818843

THALOMID REMS module



THALOMID REMS™



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For additional information about the THALOMID REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436

Announcing the new Celgene REMS mobile app for CelgeneRiskManagement.com! Download to your iPad here:



Welcome to the THALOMID REMS™ program

THALOMID® (thalidomide) in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma (MM).

THALOMID is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL).

THALOMID is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis.

THALOMID is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

Important information about THALOMID and the THALOMID Risk Evaluation and Mitigation Strategy (REMS)™ program

- THALOMID is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with THALOMID provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, THALOMID is only available under a restricted distribution program called "THALOMID REMS™" (formerly known as the S.T.E.P.S.® program)
- Only prescribers and pharmacies certified by the THALOMID REMS™ program can prescribe and dispense THALOMID to patients who are enrolled and meet all the conditions of the THALOMID REMS™ program

The goals of the THALOMID risk evaluation and mitigation strategy are as follows:

1. To prevent the risk of embryo-fetal exposure to THALOMID
2. To inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for THALOMID


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To avoid embryo-fetal exposure, THALOMID is only available under a restricted distribution program called "THALOMID Risk Evaluation and Mitigation Strategy (REMS)™" (formerly known as the S.T.E.P.S.® program). Only certified prescribers can prescribe THALOMID and only certified pharmacies can dispense THALOMID in the THALOMID REMS™ program.

In order to receive THALOMID, all patients must be enrolled in the THALOMID REMS™ program and agree to comply with the requirements of the THALOMID REMS™ program.

Key points of the THALOMID REMS™ program

Prescriber

- The prescriber enrolls and becomes certified with Celgene for the THALOMID REMS™ program
- The prescriber counsels patient on benefits and risks of THALOMID
- The prescriber provides contraception and emergency contraception counseling
- The prescriber verifies negative pregnancy test for all female patients of reproductive potential
- The prescriber completes a THALOMID® (thalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene
- The prescriber/patient completes applicable mandatory confidential survey
- The prescriber obtains an authorization number from Celgene and writes it on every prescription, along with the patient risk category
- The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- The prescriber sends THALOMID prescription to certified pharmacy

Pharmacy

- The pharmacy certifies with Celgene for the THALOMID REMS™ program
- The certified pharmacy must obtain a confirmation number from Celgene before dispensing
- The certified pharmacy counsels the patient, and completes the Education and Counseling Checklist
- The certified pharmacy dispenses THALOMID to patient along with a Medication Guide

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Prescriber Resources

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Enrolling in THALOMID REMS™

In order to prescribe THALOMID, you must enroll in the THALOMID REMS™ program (formerly known as the S.T.E.P.S.® program) and agree to follow the requirements of the program. You can enroll by visiting CelgeneRiskManagement.com, a website that allows prescribers to handle the REMS process for all of the Celgene REMS programs. You can also download the Prescriber Enrollment Form below and fax it to Celgene Customer Care at 1-888-432-9325.

[Prescriber Enrollment Form](#)

Prescribing THALOMID for your patients

In order to receive THALOMID, your patients must also be enrolled in the THALOMID REMS™ program. You can enroll your patients and fill out a prescription form using CelgeneRiskManagement.com. You and your patients can also complete your mandatory confidential surveys there.

Additionally, you can also enroll your patients and write prescriptions by downloading the Desktop Software and installing it on your computer.

[Enroll Your Patients at Celgene REMS mobile app](#)

[Download the Celgene REMS mobile app](#)

[Patient Prescription Form](#)

[Desktop Software Installation](#)

[Installation User Guide](#)

Learning more about THALOMID REMS™

For a complete overview of the THALOMID REMS™ program, and a guide to the THALOMID REMS™ process, please see the educational materials below.

[Prescriber Guide to THALOMID REMS™ Program](#)

[THALOMID REMS™ At-A-Glance](#)

[Full Prescribing Information](#)

Please report adverse drug experiences that are suspected to be associated with the use of THALOMID and any suspected pregnancy occurring during the treatment with THALOMID to Celgene using any of the following methods:

REPORTING TO CELGENE

Email: drugsafety@celgene.com

Telephone: 1-908-673-9667

Toll-free: 1-800-640-7854 (Global Drug Safety & Risk Management) or 1-888-423-5436 (Celgene Customer Care Center)

Fax: 1-908-673-9115

Mail to: Global Drug Safety & Risk Management
Celgene Corporation
300 Connell Dr.
Suite 6000
Berkeley Heights, NJ 07922

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of THALOMID and any suspected pregnancy occurring during the treatment with THALOMID may also be reported to the FDA MedWatch Reporting System using any of the following methods:

Online: <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>

Telephone: 1-800-332-1088

Fax: 1-800-332-0178

Mail to: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

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Online: <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>

Telephone: 1-800-332-1088

Fax: 1-800-332-0178

Mail to: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9757

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Patient Resources

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What you need to know about the THALOMID REMS™ program

Your doctor will enroll you in the THALOMID REMS™ program (formerly known as the S.T.E.P.S.® program) so that you can receive your medication. Use the materials below to learn more about the THALOMID REMS™ program, and what you need to do.

[Patient Guide to THALOMID REMS™ Program](#)



[Patient Survey Reminder Card](#)



[Patient Medication Guide](#)



[Visit Planned Parenthood site for Emergency Contraception Brochure](#)

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THALOMID REMS™ information for certified pharmacies

THALOMID is only dispensed from THALOMID REMS™ program (formerly known as the S.T.E.P.S.® program) certified pharmacies. To learn more about how to become a certified pharmacy, please contact the Celgene Customer Care Center at 1-888-423-5436.

As a THALOMID REMS™ certified pharmacy, you must follow the requirements of the THALOMID REMS™ program. You may download a guide to the program, a checklist for counseling patients, and the full prescribing information below.

Pharmacy Guide to THALOMID REMS™ Program

Education and Counseling Checklist for Pharmacies

Full Prescribing Information

The Celgene REMS Pharmacy Portal

In addition to calling the Celgene Customer Care Center to obtain a confirmation number for a prescription, eligible pharmacies can obtain confirmation numbers using the Celgene REMS Pharmacy Portal at CelgeneREMSPharmacyPortal.com. Contact your Celgene Account Manager to see if your pharmacy is eligible.

Celgene REMS Pharmacy Portal

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